

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Wolfe *et al.*

Confirmation No.: Not yet assigned

Appl No.: 10/750,076

Group Art Unit: Not yet assigned

Filed: December 31, 2003

Examiner: Not yet assigned

For: METHODS OF PROTEIN PURIFICATION AND RECOVERY

February 3, 2004

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

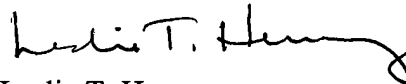
INFORMATION DISCLOSURE STATEMENT  
CITATION UNDER 37 C.F.R. § 1.97

Attached is a list of documents on form PTO-1449.

It is requested that the Examiner consider these documents and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP. By submitting the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead submitting the listed documents for the sake of full disclosure.

All cited documents were supplied in parent Application No. 10/035,420, filed October 25, 2001. Since the benefit of this application was claimed under 35 U.S.C. 120, no copies need to be furnished in accordance with 37 C.F.R. 1.98(d); however, copies will be furnished on request.

Respectfully submitted,



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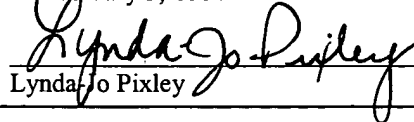
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Lynda Jo Pixley

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

## Complete if Known

Application Number	10/750,076
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First Named Inventor	Wolfe
Group Art Unit	Not yet assigned
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Attorney Docket Number	PP16022.017 (35784/271881)

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## U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
	1	US-4,462,940	07-31-1984	Hanisch <i>et al.</i>	
	2	US-4,816,440	03-28-1989	Thomson, J.W.	
	3	US-4,894,330	01-16-1990	Hershenson <i>et al.</i>	
	4	US-4,931,543	06-05-1990	Halenbeck <i>et al.</i>	
	5	US-4,992,271	02-12-1991	Fernandes <i>et al.</i>	
	6	US-5,162,507	11-10-1992	Wolfe <i>et al.</i>	
	7	US-5,643,566	07-01-1997	Hanisch <i>et al.</i>	
	8	US-5,702,699	12-30-1997	Hanisch <i>et al.</i>	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
	9	EP 0 217 645 B1	04-08-1987	Cetus Corporation		
	10	EP 0 270 799 B1	06-15-1988	Cetus Oncology Corporation		
	11	EP 0 360 937	04-04-1990	Cetus Corporation		
	12	KR 9 306 706 B	07-23-1993	Lucky Ltd.		
	13	EP 0 215 658 B1	06-01-1994	Cetus Oncology Corporation		
	14	WO 95/31479	11-23-1995	Inhale Therapeutic Systems, Inc.		
	15	WO 98/27211	06-25-1998	Universidade Federal De Minas Gerais		
	16	WO 02/080976	10-17-2002	Chiron Corporation		

Examiner Signature		Date Considered	
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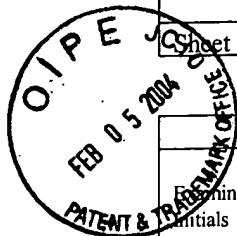
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Sheet 2 of 3



## **OTHER DOCUMENTS**

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	17	AHN, J., <i>et al.</i> , "Investigation of Refolding Condition for Pseudomonas Fluorescens Lipase by Response Surface Methodology," <i>J. Biotechnol.</i> , 1997, pp. 151-160, Vol. 54(3).	
	18	BAM, N., <i>et al.</i> , "Molten Globule Intermediate of Recombinant Human Growth Hormone: Stabilization with Surfactants," <i>Biotechnol. Prog.</i> , 1996, pp. 801-809, Vol. 12(6).	
	19	CARPENTER, J., and J.H. CROWE, "The Mechanism of Cryoprotection of Proteins by Solutes," <i>Cryobiology</i> , 1988, pp. 244-255, Vol. 25(3).	
	20	CHARMAN, S., <i>et al.</i> , "Techniques for Assessing the Effects of Pharmaceutical Excipients on the Aggregation of Porcine Growth Hormone," <i>Pharm. Res.</i> , 1993, pp. 954-962, Vol. 10(7).	
	21	CLELAND, J., <i>et al.</i> , "Polyethylene Glycol Enhanced Protein Refolding," <i>Biotechnology</i> , 1992, pp. 1013-1019, Vol. 10(9).	
	22	DAUGHERTY, D., <i>et al.</i> , "Artificial Chaperone-Assisted Refolding of Citrate Synthase," <i>J. Biol. Chem.</i> , 1998, pp. 33961-33971, Vol. 273(51).	
	23	DRYDEN, D., and M.P. WEIR, "Evidence for an Acid-Induced Molten-Globule State in Interleukin-2; A Fluorescence and Circular Dichroism Study," <i>Biochim. Biophys. Acta</i> , 1991, pp. 94-100, Vol. 1078(1).	
	24	EDY, V., <i>et al.</i> , "Stabilisation of Mouse and Human Interferons by Acid pH Against Inactivation Due to Shaking and Guanidine Hydrochloride," <i>Proc. Soc. Exp. Biol. Med.</i> , 1974, pp. 249-253, Vol. 146(1).	
	25	EDY, V., <i>et al.</i> , "Stable and Unstable Forms of Human Fibroblast Interferon," <i>Infect. Immun.</i> , 1977, pp. 445-448, Vol. 16(2).	
	26	GAUTHIER, M., and P.A. PATSTON, "Reactivation of C1-Inhibitor Polymers by Denaturation and Gel-Filtration Chromatography," <i>Anal. Biochem.</i> , 1997, pp. 228-233, Vol. 248(2).	
	27	HOURY, W., <i>et al.</i> , "The Nature of the Initial Step in the Conformational Folding of Disulphide-Intact Ribonuclease A," <i>Nat. Struct. Biol.</i> , 1995, pp. 495-503, Vol. 2(6).	
	28	JARIWALLA, R., <i>et al.</i> , "The Reactivation of Human Interferons by Guanidine Thiocyanate," <i>Experientia</i> , 1980, pp. 1390-1391, Vol. 36(12).	

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Examiner Initial	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	29	KENDRICK, B., <i>et al.</i> , "Quantitation of the Area of Overlap Between Second-Derivative Amide I Infrared Spectra to Determine the Structural Similarity of a Protein in Different States," <i>J. Pharm. Sci.</i> , 1996, pp. 155-158, Vol. 85(2).	
	30	LEE, J.K., <i>et al.</i> , "Purification of Human Interferon- $\beta$ from Recombinant <i>E. coli</i> ," <i>Korean Biochemical Journal</i> , 1990, pp. 166-171, Vol. 23(2).	
	31	MUZAMMIL, S., <i>et al.</i> , "Molten Globule-Like State of Human Serum Albumin at Low pH," <i>Eur. J. Biochem.</i> , 1999, pp. 26-32, Vol. 266(1).	
	32	PEPINSKY, R.B., "Selective Precipitation of Proteins from Guanidine Hydrochloride-Containing Solutions with Ethanol," <i>Analytical Biochemistry</i> , 1991, pp. 177-181, Vol. 195.	
	33	ROZEMA, D., and S.H. GELLMAN, "Artificial Chaperone-Assisted Refolding of Denatured-Reduced Lysozyme: Modulation of the Competition Between Renaturation and Aggregation," <i>Biochemistry</i> , 1996, pp. 15760-15771, Vol. 35(49).	
	34	ROZEMA, D., and S.H. GELLMAN, "Artificial Chaperone-Assisted Refolding of Carbonic Anhydrase B," <i>J. Biol. Chem.</i> , 1996, pp. 3478-3487, Vol. 271(7).	
	35	RUSSELL-HARDE, D., <i>et al.</i> , "The Use of Zwittergent 3-14 in the Purification of Recombinant Human Interferon- $\beta$ Ser <sup>17</sup> (Betaseron)," <i>Journal of Interferon and Cytokine Research</i> , 1995, pp. 31-37, Vol. 15(1).	
	36	TODHUNTER, R., <i>et al.</i> , "Structure of Equine Type I and Type II Collagens," <i>Am. J. Vet. Res.</i> , 1994, pp. 425-431, Vol. 55(3).	
	37	VAN OSS, C.J., "On the Mechanism of the Cold Ethanol Precipitation Method of Plasma Protein Fractionation," <i>Journal of Protein Chemistry</i> , 1989, pp. 661-668, Vol. 8(5).	
	38	WEIR, M., <i>et al.</i> , "Micropreparative Purification of Recombinant Human Interleukin-2," <i>J. Chromatogr.</i> , 1987, pp. 209-215, Vol. 396.	
	39	XIE, Y. and D. B. WETLAUFER, "Control of Aggregation in Protein Refolding: The Temperature-Leap Tactic," <i>Protein Sci.</i> , 1996, pp. 517-523, Vol. 5(3).	

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